

Sheet

PTO/SB/08B (08-03) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

1

Complete if Known				
Application Number	09/900,364			
Filing Date	July 5, 2001			
First Named Inventor	Paul D. van Poelje			
Group Art Unit	1617			
Examiner Name	Leonard M. Williams			
Attorney Docket Number	MET-037CXT			

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/LW/	R1	VAN POELJE, PAUL D. et al. "Combination Therapy with Pioglitazone and a Fructose-1,6-bisphosphatase Inhibitor (MB06322; CS-917) Improves Glycaemic Control and Lactate Homeostasis in Male Zucker Diabetic Fatty (ZDF) Rates" poster presented at the European Association for the Study of Diabetes (EASD), Copenhagen, Denmark, September 14-17, 2006.	
	R2		
	R3	·	
	R4		
	R5		
	R6		
-	R7		
	R8		
	R9		
	R10		
	R11		
	R12	<u>I</u>	

Examiner	/Leonard Williams/ (10/15/2007)	Date	
Signature		Considered	L
PEVANUALED LAWEL	for the second s	O Denny Ban the	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

1

PTO/SB/08A (08-03) Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

MET-037CXT

Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Complete if Known Substitute for form 1449A/PTO **Application Number** 09/900,364 INFORMATION DISCLOSURE **Filing Date** July 5, 2001 STATEMENT BY APPLICANT **First Named Inventor** Paul D. van Poelje (use as many sheets as necessary) **Art Unit** 1617 **Examiner Name** Leonard M. Williams of Sheet **Attorney Docket Number**

			U.S. PATENT D	JCUMEN 19	
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/LW/	U1	US-4,968,790	11-06-1990	DeVries et al.	All
/LW/	U2	US-5,728,704	03-17-1998	Mylari et al.	All
/LW/	U3	US-4,278,791	07-14-1981	Botta et al.	All
/LW/	U4	US-5,342,850	08-30-1994	Ohnota et al.	All
/LW/	U5	US-6,147,101	11-14-2000	Maeda et al.	All
	U6	US-			
	U7	US-	<u> </u>		
	U8	US-			
	U9	US-	1		

6

		FOREIGN	PATENT DOCL	JMENTS		
Examiner Initiats*	Cite No. '	Foreign Patent Document Country Code 3 - Number 4 - Kind Code 5 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	7*
/LW/	F1	EP 0354322	06-16-1989	American Cyanamid Company	All	
/LW/	F2	WO 99/45016	09-10-1999	Metabasis Therapeutics, Inc.	All	
/LW/	F3	WO 90/08155	07-26-1990	Board of Regents- University of Texas	All	
/LW/	F4	WO 90/10636	09-20-1990	Board of Regents- University of Texas	All	
	F5					
	F6					
-	F7					

Examiner Signature	/Leonard Williams/ (10/15/2007)	Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (08-03) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE rwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Complete if Known

09/900,364

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Filing Date First Named Inventor Group Art Unit

Application Number

July 5, 2001 Paul D. van Poelje 1617 Leonard M. Williams

(use as many sheets as necessary)

Examiner Name Attorney Docket Number MET-037CXT Sheet of 6

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/LW/	R1	AZEN, S.P. et al., "TRIPOD (TRoglitazone In the Prevention of Diabetes): A Randomized, Placebo-Controlled Trial of Troglitazone in Women with Prior Gestational Diabetes Mellitus," Controlled Clinical Trials, Vol. 19, Issue 2, Pages 217-231, Elsevier B.V. (April 1998).	
/LW/	R2	CHIASSON, JL. et al., "Acarbose for the prevention of Type 2 diabetes, hypertension and cardiovascular disease in subjects with impaired glucose tolerance: facts and interpretations concerning the critical analysis of the STOP-NIDDM Trial data," Diabetologia, 47: 969-975, Springer-Verlag (2004).	
/LW/	R3	DELORME, S. et al., "Acarbose in the prevention of cardiovascular disease in subjects with impaired glucose tolerance and type 2 diabetes mellitus," Current Opinion in Pharmacology, 5:184-189, Elsevier (2005).	
/LW/	R4	DICKSON, J.K. et al., "Orally Active Squalene Synthase Inhibitors: Bis((acyloxy)alkly) Prodrugs of the α-Phosphonosulfonic Acid Moiety" J. Med. Chem. 39: 661-664 American Chemical Society (1996).	
/LW/	R5	EGRON, D. et al., "Synthesis and Anti-HIV Activity of Some S-Acyl-2-Thioethyl (Sate) Phosphoramidate Derivatives of 3'-Azido-2',3'Dideoxythymidine" Nucleosides & Nucleotides 18(4&5): 981-982 Marcel Dekker, Inc. (1999).	
/LW/	R6	ERION, M.D. et al., "Computer-Assisted Scanning of Ligand Interactions: Analysis of the Fructose 1,6-Bisphosphatase-AMP Complex Using Free Energy Calculations" J. Am. Chem. Soc. 122:6114-6115 American Chemical Society (2000).	
/LW/	R7	ERION, M.D. and REDDY, M.R. "Ligand Interaction Scanning Using Free Energy Calculations" <i>Free Energy Calculations in Rational Drug Design</i> , Chapter 11, 225-241 Springer-Verlag (2001).	
/LW/	R8	ERION, M.D. et al., "MB06322 (CS-917): A Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase for Controlling Gluconeogenesis in Type 2 Diabetes" <i>PNAS</i> 102(22): 7970-7975 (May 2005).	
/LW/	R9	FISHER, J.S. et al., "Glucose transport rate and glycogen synthase activity both limit skeletal muscle glycogen accumulation," The American Journal of Physiology Endocrinol. Metab., Vol. 282, pp. E1214-E1221, American Physiological Society (June 2002).	
/LW/	R10	FUJIWARA, T. et al., "Suppression of Hepatic Gluconeogenesis in Long-Term Troglitazone Treated Diabetic KK and C57BL/KsJ-db/db Mice" Metabolism 44(4): 486-490 (April 1995).	

Examiner	//	Date	1
Signature	/Leonard Williams/ (10/15/2007)	Considered	J

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO). gathering, preparing, and submitting the completed application form to the uSPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



Sheet

PTO/SB/08B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Eduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Substitute for form 1449B/PTO
INFORMATION DISCLO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

3 of 6

Complete If Known				
Application Number	09/900,364			
Filing Date	July 5, 2001			
First Named Inventor	Paul D. van Poelje			
Group Art Unit	1617	_		
Examiner Name	Leonard M. Williams			
Attorney Docket Number	MET-037CXT	7		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/LW/	R11	GIDH-JAIN, M. et al., "The Allosteric Site of Human Liver Fructose-1,6-Bisphosphatase" Journal of Biological Chemistry, 269(44): 27732-27738 The American Society for Biochemistry and Molecular Biology, Inc. (1994).	
/LW/	R12	HOLMAN, R.R. "Assessing the potential for α-glucosidase inhibitors in prediabetic states," Diabetes Research and Clinical Practice, Vol. 40, Supp. 1, Pages 21-25, Elsevier Ireland Ltd. (July 1998).	
/LW/	R13	HOWARD, G. et al., "Insulin Sensitivity and Atherosclerosis" Circulation 93(10): 1809-1817 (May 15, 1996).	
/LW/	R14	HULLEY, S. et al., "Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women," J. of Am. Medical Assoc., Vol. 280, No. 7, pp. 605-613 (August 19, 1998).	
/LW/	R15	LINK, J.T. et al., "Pharmacological regulation of hepatic glucose production," Curr. Opin. Investig. Drugs, 4(4):421-9, (April 2003).	
/LW/	R16	MAGGS, D.G. et al., "Metabolic Effects of Troglitazone Monotherapy in Type 2 Diabetes Mellitus" Annals of Internal Medicine 128(3):176-185 American College of Physicians (February 1, 1998).	,
/LW/	R17	MARYANOFF, B. E. et al., "Stereoselective Synthesis and Biological Activity of β- and α-D-Arabinose 1,5-Diphosphate: Analogues of a Potent Metabolic Regulator" <i>J. Am. Chem. Soc.</i> 106:7851-7853 (1984).	
/LW/	R18	OKUNO, A. et al., "CS-917, a Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, Suppresses Gluconeogenesis In Vitro and In Vivo by a Different Mechanism than Metformin" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).	
/LW/	R19	PICKAVANCE, L. et al., "The Development of Overt Diabetes in Young Zucker Diabetic Fatty (ZDF) Rats and the Effects of Chronic MCC-555 Treatment" British Journal of Pharmacology, 125: 767-770 Stockton Press (1998).	
/LW/	R20	POTTER, S.C. et al., "Effect of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase, on Gluconeogenesis in the ZDF Rat as Assessed by the Deuterated Water Technique" DIAEAZ 52(2): A364, Journal of the American Diabetes Association Abstract No. 1516-P, American Diabetes Association (June 2004).	

Examiner Signature	/Leonard Williams/ (10/15/2007)	Date Considered
Constitution		Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO).

This collection of information is required by 37 CFR 1.98. The Information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/08B (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Complete if Known

1617

09/900,364

July 5, 2001

Paul D. van Poelje

Under the Par Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Number

First Named Inventor

Filing Date

Group Art Unit

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Examiner Name Leonard M. Williams Sheet of 6 **Attorney Docket Number** MET-037CXT

		· · · · · · · · · · · · · · · · · · ·	
	•	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the Item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/LW/	R21	POTTER, S.C. "Evidence Implicating Gluconeogenesis Inhibition as the Mechanism by Which MB06322 Lowers Blood Glucose In Vivo" <i>DIAEAZ</i> 52(2): A364, Journal of the American Diabetes Association Abstract No. 1517-P, American Diabetes Association (June 2004).	
/LW/	R22	PRISANT, L.M. "Preventing Type II Diabetes Mellitus," <i>J. Clin. Pharmacol.</i> , 44:406-413, American College of Clinical Pharmacology (2004).	
/LW/	R23	REDDY, M.R. and ERION, M.D. "Computer Aided Drug Design Strategies Used in the Discovery of Fructose 1,6-Bisphosphatase Inhibitors" <i>Current Pharmaceutical Design</i> 11: 283-294 Bentham Science Publishers Ltd. (2005).	
/LW/	R24	REDDY, K.R. et al., "Discovery of 2-Aminopyridine Inhibitors of FBPase" abstract for the 230 th National American Chemical Society (ACS) Meeting, Washington, DC, Aug./Sept. 2005, ACSMEDI Program and Abstract Book Archives, pp. 197-198, MEDI 323, obtained from http://oasys.acs.org/acs/230nm/medi/staff/separates.cgi 8/8/2005.	
/LW/	R25	REDDY, M.R. and ERION, M.D. "Fructose 1,6-Bisphosphatase: Use of Free Energy Calculations in the Design and Optimization of AMP Mimetics" Free Energy Calculations in Rational Drug Design, Chapter 14, 285-297 Springer-Verlag (2001).	
/LW/	R26	RIDDLE, M.C. "New Tactics for Type 2 Diabetes: Regimens Based on Intermediate-Acting Insulin Taken at Bedtime" <i>The Lancet</i> 192-195 (January 26, 1985).	
/LW/	R27	SATHYAPRAKASH, R. et al., "Preventing Diabetes by Treating Aspects of the Metabolic Syndrome," Current Diabetes Reports, 2:416-422, Current Science Inc. (2002).	
/LW/	R28	SCHEEN, A.J. and LEFEBVRE, P.J. "Oral Antidiabetic Agents A Guide to Selection" <i>Drugs</i> 55(2):225-236 Adis International Limited (February 1998).	
/LW/	R29	SREENAN, S. et al., "Prevention of Hyperglycemia in the Zucker Diabetic Fatty Rat by Treatment with Metformin or Troglitazone" Am. J. Physiol. 271 (Endorcinol. Metab. 34): E742-E747 American Physiological Society (1996).	
/LW/	R30	SRIVASTVA, D.N. and FARQUHAR, D. "Bioreversible Phosphate Protective Groups: Synthesis and Stability of Model Acyloxymethyl Phosphates" <i>Bioorganic Chemistry</i> 12: 118-129 Academic Press, Inc. (1984).	

Examiner		Date	
Signature	/Leonard Williams/ (10/15/2007)	Considered	
Congritation		Considered	

'EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

'Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork

Sheet

PTO/S8/08B (08-03) Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

fuction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

5

(use as many sheets as necessary)

of

6

Application Number 09/900,364 Filing Date July 5, 2001 First Named Inventor Paul D. van Poelje 1617 **Group Art Unit** Leonard M. Williams **Examiner Name** Attorney Docket Number

MET-037CXT

Complete if Known

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/LW/	R31	TORLONE, E. et al., "Improved Insulin Action and Glycemic Control After Long-Term Angiotensin-Converting Enzyme Inhibition in Subjects with Arterial Hypertension and Type II Diabetes" Diabetes Care 16(10):1347-1355 (October 1993).	
/LW/	R32	TORRES, T. et al., "Inhibition of glycogen phosphorylase suppresses basal and glucagon-induced glucose production and increases glucose uptake in the liver of conscious dogs" (Integrated Physiology—Liver 1484-P), <i>Diabetes</i> , Vol. 52 i6, p. A343, American Diabetes Association (June 2003).	
/LW/	R33	TRISCARI, J. et al., "Multiple Ascending Doses of CS-917, a Novel Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, in Subjects with Type 2 Diabetes Treated for 14 Days" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).	
/LW/	R34	TURNBULL, A. et al., "Pharmacological inhibition of glycogen phosphorylase (GP) lowers plasma glucose in rat models of type 2 diabetes. (Integrated Physiology—Liver 1485-P)," Diabetes, Vol. 52 i6, p. A343, American Diabetes Association (June 2003).	
/LW/	R35	TURNER, R.C. et al., "U.K. Prospective Diabetes Study 16: Overview of 6 Years' Therapy of Type II Diabetes, a Progressive Disease. (U.K. Prospective Diabetes Study Group)" Diabetes 44(11):1249(10) American Diabetes Association (Nov. 1995).	
/LW/	R36	UNGER, R. H. "How Obesity Causes Diabetes in Zucker Diabetic Fatty Rats" <i>Trends Endocrinol Metab</i> 7: 276-282 Elseveir Science Inc. (1998).	
/LW/	R37	VAN POELJE, P.D. et al., "Characterization of the Mechanism of Action and Antidiabetic Activity of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase" DIAEAZ 52(2): A366, Journal of the American Diabetes Association Abstract No. 1523-P, American Diabetes Association (June 2004).	
/LW/	R38	VAN POELJE, P.D., et al., "Comparative Metabolic Effects of a Novel Fructose 1,6-Bisphosphatase Inhibitor and Metformin in the Female ZDF Rat", Abstracts of the 41 st Annual Meeting of The European Association for the Study of Diabetes, Athens, Greece Diabetologia 48(1):A278 Abstract No. 765 Springer-Verlag (August 2005).	
/LW/	R39	VAN POELJE, P.D. et al., "Inhibition of Fructose 1,6-Bisphosphatase Reduces Excessive Endogenous Glucose Production and Attenuates Hyperglycemia in Zucker Diabetic Fatty Rats" <i>Diabetes</i> 55:1747-1754, American Diabetes Association (June 2006).	

Examiner	/Leonard Williams/ (10/15/2007)	Date	
Signature	/Leonard Williams/ (10/15/2007)	Considered	J

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

*Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Sheet

PTO/SB/08B (08-03)

Complete if Known

Approved for use through 07/31/2006. ONB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

6

09/900,364 **Application Number Filing Date** July 5, 2001 Paul D. van Poelje First Named Inventor **Group Art Unit** 1617 Leonard M. Williams **Examiner Name Attorney Docket Number** MET-037CXT

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
/LW/	R40	VAN POELJE, P.D. et al., "MB06322 (CS-917) Lowers Blood Glucose in Rodents by Inhibiting Both Hepatic and Renal Gluconeogenesis" <i>DIAEAZ</i> 55(1): A137, Journal of the American Diabetes Association Abstract No. 575-P, American Diabetes Association (June 2006).	
/LW/	R41	VAN POELJE, P.D. et al., "Fructose 1,6-Bisphosphatase Inihbition Enhances the Antidiabetic Activity of Insulin Sensitizers in the ZDF Rat" <i>DIAEAZ</i> 52(2): A366, Journal of the American Diabetes Association Abstract No. 1524-P, American Diabetes Association (June 2004).	
/LW/	R42_	VAN POELJE, P.D. "MB06322, a Potent Inhibitor of Gluconeogenesis, Attenuates Hyperglycemia without Causing Weight Gain or Hypoglycemia in Female Zucker Diabetic Fatty Rats" <i>DIAEAZ</i> 54(1):A124, Journal of the American Diabetes Association Abstract No. 503-P, American Diabetes Association (June 2005).	
/LW/	R43	WALKER, J. et al., "Safety and Tolerability of Single Doses of CS-917, a Novel Gluconeogenesis Inhibitor, in Normal Male Volunteers" <i>DIAEAZ</i> 55(1): A463, Journal of the American Diabetes Association Abstract No. 2002-PO, American Diabetes Association (June 2006).	
/LW/	R44	WALKER, J. et al., "Safety, Tolerability and Pharmacodynamics of Multiple Doses of CS-917 in Normal Volunteers" <i>DIAEAZ</i> 55(1): A464, Journal of the American Diabetes Association Abstract No. 2003-PO, American Diabetes Association (June 2006).	
/LW/	R45	YOSHIDA, T. et al., "Comparison of Acute and Chronic Glucose-Lowering Effect of CS- 917, a Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, and Metformin in Rat Models of Type 2 Diabetes" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).	
/LW/		YOSHIDA, T. et al., "CS-917, a Fructose 1,6-Bisphosphatase Inhibitor, Has Glucose- Lowering Effects in Cynomolgus Monkeys and Improves Postprandial Hyperglycemia in Goto-Kakizaki (GK) Rats" <i>DIAEAZ</i> 54(1): A116-A117, Journal of the American Diabetes	
	R46	Association Abstract No. 472-P, American Diabetes Association (June 2005).	\vdash
:	R47		
	R48		

Examiner	/Leonard Williams/ (10/15/2007)	Date	
Signature	/Leonard williams/ (10/15/2007)	Considered	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO). to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

JUL 2 4 2006

PTO/SB/08A (08-03)
Approved for use through 07/31/2008. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. ĎEPARTMENT OF COMMERCE U.S. ĎEPARTMENT OF COMMERCE Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substi	Substitute for form 1449A/PTO				Con	Complete if Known		
_	INFORMATION DISCLOSURE					Application Number	09/900,364	
						Filing Date	July 5, 2001	
317	STATEMENT BY APPLICANT					First Named Inventor	Paul D. van Poelje	
	(use as many sheets as necessary)					Art Unit	1617	
						Examiner Name	Leonard M. Williams	
She	et	1	of		1	Attorney Docket Number	MET-037CXT	

Examiner	ner Cite	Document Number	Publication Date	Name of Patentee or Applicant	Pages, Columns, Lines, Where
Initials*	No. 1	Number - Kind Code ² (if known)	MM-DD-YYYY		Relevant Passages or Relevant Figures Appear
/LW/	U1	US-6,756,360	06-29-2004	Erion et al.	All
/LW/	U2	US-6,919,322	07-19-2005	Bookser <i>et al</i> .	All
/LW/	U3	US-6,965,033	11-15-2005	Jiang et al.	All
/LW/	U4	US-6,967,193	11-22-2005	Dang et al.	All
/LW/	U5	US-2004/0167178	08-26-2004	Erion et al.	All
/LW/	U6	US-2005/0004077	01-06-2005	Jiang et al.	All
/LW/	U7	US-2004/0058892	03-25-2004	Dang et al.	All
/LW/	U8	US-2005/0176684	08-11-2005	Bookser et al.	All
	U9				

		Foreign Patent Document				
Examiner Initials*	Cite No. 1	Country Code 3 - Number 4 - Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	 T*
/LW/	F1	WO 01/47935 CD-ROM	07-05-2001	Metabasis Therapeutics	All	
/LW/	F2	WO 01/66553 CD-ROM	09-13-2001	Metabasis Therapeutics	All	
/LW/	F3	WO 02/03978 CD-ROM	01-17-2002	Metabasis Therapeutics	All	
/LW/	F4	WO 06/023515 CD-ROM	03-02-2006	Metabasis Therapeutics	All	
	F5					

Examiner	(1 1140)	Date	
Signature	/Leonard Williams/ (10/15/2007)	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.